Supreme Court, U.S.
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No. 93-1895

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

RYAN THOMAS, a minor by Roberta Thomas and Ronald C. Thomas, Jr., his natural parents and guardians,
Petitioner,

vs.

PAUL D. ZUBRITZKY and THE UPJOHN COMPANY and MERRELL DOW PHARMACEUTICALS, INC.
Respondents.

THE UPJOHN COMPANY'S BRIEF IN OPPOSITION TO THE PETITION FOR A WRIT OF CERTIORARI TO THE SUPERIOR COURT OF PENNSYLVANIA

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

Whether this Court should review a state court decision based on state law to address a claimed due process violation asserted for the first time in the Petition for Certiorari in this Court and not preserved for review in the courts below.

Whether the United States Constitution's Due Process Clause permits a state to award summary judgment against a litigant who, despite notice and an opportunity to be heard, fails to make an adequate showing under state law of a sufficient question of fact to prevent summary judgment.

Whether the United States Constitution requires the individual states to adopt federal standards for the admission of evidence and the granting of summary judgment.

STATEMENT PURSUANT TO RULE 29.1

The following is a list of Upjohn subsidiaries that are not wholly owned subsidiaries of either The Upjohn Company or any of its subsidiaries:

Admiral Espanola, S.A.
Asgrow Mexicana, S.A. de C.V.
Ceres, S.A. de C.V.
Cobb Breeding
Cobb-Vantress, Inc.
Complejo Asgrow Semillas - S.A.
Horticultura de Salama
Japan Upjohn Limited
Korea Upjohn Ltd.
P.T. Upjohn Indonesia
Saudi Urethan Chemical Company, Ltd. (SUCCO)
Unipharma S.A.
Upjohn Pakistan (Private) Limited
Yusafarm d.o.o.

Upjohn does not have a corporate parent.

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BRIEF IN OPPOSITION

The Upjohn Company ("Upjohn"), a respondent herein, respectfully submits this Brief in Opposition to the Petition for Certiorari in the instant case.

OPINIONS BELOW

Respondent Upjohn adopts petitioners' statement concerning the opinions below, but notes that the Superior Court affirmance of the Court of Common Pleas is reported in table form (no opinion) at 427 Pa. Super. 656; 625 A.2d 100 (Pa. Super 1992).

JURISDICTIONAL STATEMENT

Petitioners assert jurisdiction pursuant to 28 U.S.C. § 1257 (a). Respondent Upjohn disputes this assertion. As set forth more

fully in the instant Brief in Opposition, this is a claim involving only questions of state law and this Court has no jurisdiction to entertain it.

RELEVANT STATUTES AND OTHER PROVISIONS NOT QUOTED OR NOT QUOTED IN FULL IN PETITION

Federal Rule of Civil Procedure 56 (e): Form of Affidavits; Further Testimony; Defense Required. Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. Sworn or certified copies of all papers or parts thereof referred to in an affidavit shall be attached thereto or served therewith. The court may permit affidavits to be supplemented or opposed by depositions, answers to interrogatories, or further affidavits. When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

Federal Rule of Evidence 705: The expert may testify in terms of his opinion or inference and give reasons therefor without first testifying to the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts and data on cross-examination.

Pennsylvania Rule of Civil Procedure 1035: Motion for Summary Judgment.

(a) After the pleadings are closed, but within such time as not to delay trial, any party may move for summary judgment on the pleadings and any depositions, answers to interrogatories, admissions on file and supporting affidavits.

(b) The adverse party, prior to the day of hearing, may serve opposing affidavits. The judgment sought shall be rendered if

the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary judgment, interlocutory in character, may be rendered on the issues of liability alone although there is a genuine issue as to the amount of damages.

(c) If on motion under this rule judgment is not rendered upon the whole case or for all the relief asked and a trial is necessary, the court at the hearing of the motion, by examining the pleadings and the evidence before it and by interrogating counsel, shall if practicable ascertain what material facts exist without substantial controversy and what material facts are actually and in good faith controverted. It shall thereupon make an order specifying the facts that appear without substantial controversy, including the extent to which the amount of damages or other relief is not in controversy and directing such further proceedings in the action as are just. Upon the trial of the action the facts so specified shall be deemed established, and the trial shall be conducted accordingly.

(d) Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the signer is competent to testify to the matters stated therein. Verified or certified copies of all papers or parts thereof referred to in an affidavit shall be attached thereto or served therewith. The court may permit affidavits to be supplemented or opposed by depositions, answers to interrogatories, or further affidavits. When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If he does not so respond, summary judgment, if appropriate, shall be entered against him.

(e) Should it appear from the affidavits of a party opposing the motion that he cannot for reasons stated present by affidavit

facts essential to justify his opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just.

(f) Should it appear to the satisfaction of the court at any time that any of the affidavits presented pursuant to this rule are presented in bad faith or solely for the purpose of delay, the court shall forthwith order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused him to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt.

STATEMENT OF FACTS

This action was brought under Pennsylvania law by Pennsylvania residents in that state's courts. It arose out of spina bifida, hydrocephalus and Arnold-Chiari malformation[1] that Ryan Thomas was found to have suffered when he was born on February 24, 1984.

a.) The first state court suit — voluntarily dismissed for want of expert evidence

In 1985, Ryan, through his parents, Roberta and Ronald Thomas, ("Petitioners") commenced an action against respondent Paul D. Zubritzky[2], M.D., who had been treating Mrs. Thomas for infertility related to menstrual irregularities. Dr. Zubritzky had prescribed both Provera, a progestin[3] manufactured

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[1] These are different manifestations of a neural tube defect, i.e, .a developmental problem with the embryonic central nervous system.

[2] Dr. Zubritzky's name has been spelled in various ways in various papers in this record. This is the spelling used by his counsel and is presumably the correct one.

[3] A progestin is a synthetic analog of the naturally occurring hormone progesterone. It is sometimes — as in the lower court opinions here — less accurately referred to simply as a progesterone.

by respondent Upjohn, and Clomid, an estrogen manufactured by Merrell-Dow Pharmaceuticals. The lawsuit claimed improper administration of the medications and was voluntarily discontinued in 1988.[4]

b.) The second state court suit – Court of Common Pleas: Motion for Summary Judgment granted.

In 1989, respondents engaged new counsel who commenced a new action against Dr. Zubritzky on the same allegations. Dr. Zubritzky, in turn, joined Upjohn and Merrell-Dow as defendants.[5]

In August of 1991, both pharmaceutical companies moved for summary judgment on the issue of causation. Upjohn also sought summary judgment on the warning claim asserted against it. In support of their motion, both pharmaceutical defendants produced extensive evidence. Upjohn submitted the affidavits of Dr. Arthur Haney and Dr. Harold Halvorson, both of which stated that, to a reasonable degree of medical certainty, Provera does not cause neural tube defects of the type sustained by Ryan Thomas. Dr. Haney supported his opinion with references to numerous studies that had concluded that neither Provera nor the class of drugs to which it belongs causes neural tube defects. Dr. Halvorson, Upjohn's Associate Director of Medical Research, based his opinion on his experience with the drug, including the medical monitoring he conducted as part of his work for the company. Upjohn also provided the trial court with FDA's proposed revisions for the Guideline Labeling Texts for Progestational Drug Products. These proposed revisions specifically deleted the warning of a possible association between Provera and non-genital birth defects. In addition to these

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[4] The Superior Court noted that this took place on the eve of jury selection and was due to Petitioners' inability to produce expert opinions to support their claim. *See* Superior Court opinion reproduced in Appendix to Petition for Certiorari ("*App.*").

[5] Merrell-Dow settled the claim against it after it was awarded summary judgment below. It is no longer a party to this litigation.

materials, Upjohn provided a copy of the FDA committee conference at which the committee members discussed the study results that had led to the proposed revised labeling and copies of the articles and epidemiological and scientific studies that the FDA committee and Dr. Haney had relied upon. *App.* 15a-16a.

Merrell-Dow supported its motion with an affidavit from Dr. James Mills, a pediatric epidemiologist, and a letter to Mr. and Mrs. Thomas from Dr. Mark Steele, a geneticist. Dr. Mills opined that Ryan's birth defects were not caused by Clomid and noted that Mrs. Thomas had a maternal aunt who had died in infancy from spina bifida and that Mr. Thomas was of Welsh-Irish ancestry – both ethnic groups with higher rates of neural tube defects than others. Dr. Steele had been consulted by the Thomases about the risk of having another child with birth defects and had advised them that Ryan's defects were not induced by Provera and Clomid, but by a variety of factors including Mr. Thomas's ancestry and his wife's family history. *App.* 18a, n.17.

Dr. Zubritzky also moved for summary judgment, relying on the materials submitted by both manufacturers. *ibid.*

In response to this motion practice, petitioners submitted "a two-paragraph memorandum in which they baldly asserted that vast amounts of literature supported their claim that Provera caused the birth defects sustained by Ryan." Superior Court opinion, *App.* 11a. They also included a letter from Allen S. Goldman, M.D. This letter is reproduced at *App.* 34a-36a and consists of a lengthy recounting of medical history followed by two paragraphs in which Dr. Goldman wrote that it was his "considered opinion" that Ryan's birth defects were related to his *in utero* exposure to the medications, but cited no literature and referred to none of the arguments advanced by the summary judgment movants.

The trial court granted summary judgment to Upjohn and Merrell-Dow on September 19 and 30, 1991.

c.) Proceedings in the Court of Common Pleas after summary judgment was awarded – plaintiff attempted to supplement the record.

After summary judgment was granted, petitioners filed a motion for reconsideration, attaching a letter from Dr. David Abramson, reproduced at *App.* 41a-42a, dated September 8, 1991 (over a month after the manufacturers' motions had been filed). This letter made no reference to the companies' arguments or to any specific literature. It stated the doctor's "very strong opinion that standard avoidance of fetal Provera exposure would probably have prevented [Ryan's] Arnold-Chiari II malformation." *App.* 42a. It did not mention spina bifida or hydrocephalus.

The motion for reconsideration was denied on October 8, 1991.

On October 10, 1991, *after* summary judgment had been granted and reconsideration denied, petitioners filed a third document with the trial court. This was entitled "Plaintiffs' Response to Additional Defendants, Merrell-Dow Pharmaceuticals and the Upjohn Company's Motions for Summary Judgment." App. 12a. This document included the two letters already described plus two other letters from Dr. Goldman, written in 1985 and 1986 (*App.* 37a-40a). Dr. Goldman's 1985 letter referred to some literature but neither the 1985 nor the 1986 letter addressed any of the arguments raised by the defendants in their motions in September of 1991.

On January 14, 1992, the trial court issued a memorandum opinion (*App.* 31a-33a) in which it explained the basis of its ruling: the pharmaceutical defendants had made a *prima facie* showing that there was no material question of fact on causation and petitioners had failed to come forward with evidence of sufficient quality to show that there was any such question.[6]

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[6] The court had clarified its September 19 Order on September 30 to encompass the warning claims asserted against Upjohn. Since Dr. Zubritzky's liability

(Footnote continued)

d.) Plaintiffs appeal to the Superior Court – held that summary judgment on causation and warnings properly granted: plaintiffs failed to meet the threshold required to defeat summary judgment in Pennsylvania, evidence introduced in untimely fashion may not be considered.

On appeal, the Pennsylvania Superior Court upheld the summary judgment. It noted that petitioners had had the opportunity either to include the additional letters in opposition to the initial motion or to seek a continuance to secure additional reports, *App.* 12a-14a, but had not done so. Accordingly, under Pennsylvania case law, the additional letters were not properly considered in opposition to summary judgment and the only issue on the branch of the motion addressed to causation was whether Dr. Goldman's January 2, 1986, letter was sufficient to rebut the *prima facie* showing on causation made by the pharmaceutical defendants. Since Dr. Goldman's letter set forth only a conclusion with no explication of a medical basis and no discussion of the arguments or authorities raised in support of summary judgment, the court held that this was insufficient under Pennsylvania law to show a disputed issue of fact on causation. *App.* 19a. The trial court's ruling that the warnings here were adequate as a matter of law, *App.* 27a, was also upheld. Neither petitioners nor Dr. Zubritzky made any showing that there was a substantially higher risk of defects than that reported in the warning and the doctor testified at deposition that he was familiar with the insert and the literature and used the product as instructed in the insert. *App.* 24a. Thus, there was neither a failure to warn nor any showing of harm from any alleged failure. *ibid.*

e.) Pennsylvania Supreme Court – leave to appeal (allocatur) denied

Petitioners' Petition for Allowance of Appeal (Allocatur) to the Pennsylvania Supreme Court was denied on February 15, 1994.

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was predicated upon his administration of the medications in issue, summary judgment for the manufacturers ended the liability claim against him. He was granted summary judgment on October 17, 1991. Petition 6.

REASONS WHY CERTIORARI SHOULD BE DENIED

I. THIS CASE PRESENTS NO FEDERAL QUESTION

This court has long recognized that it lacks the jurisdiction to review state court decisions based on state law, regardless of whether it views them as erroneous or not. This case is a state law claim brought in state courts. It went through the entire Pennsylvania court system without the words "due process" being addressed to, or used by, a court. The purported presentation of the federal constitutional issue to the Pennsylvania courts was procedurally defective under that state's law. What was presented to the Pennsylvania Supreme Court was utterly inadequate to alert that court to the existence of any federal constitutional claim. It did not even hint at the due process violation alleged in the Petition.

a.) The arguments and decisions below were based on state law.

Petitioners, as required by Rule 14.1 (h) of this Court, identified "the method or manner of presenting the federal question sought to be reviewed and raised here" on page 8 of their Petition. The applicable statement reads in full as follows:

> On January 15, 1993, Petitioner [sic] filed a Petition for Allowance of Appeal to the Supreme Court of Pennsylvania stating that "The Superior Court had decided a question of substance in a manner not in accord with and contrary to applicable decisions of the Supreme Court of Pennsylvania and the Supreme Court of the United States," and in doing so presented the federal question. (Petitioner's Petition for Allowance of Appeal p.5.).

Petitioners cannot point to anything in the record that shows that they raised, or the lower courts decided, any question of federal law. The trial court's decisions, reproduced in the Appendix to the Petition, are totally silent on the subject of federal law. The Superior Court opinion, also reproduced in the Appendix, is likewise silent on federal questions. Instead, it addresses four issues:

a.) the standard of review of summary judgment proceedings under Pennsylvania law, App. 10a-11a (citing Pennsylvania Supreme Court and Superior Court constructions of Pennsylvania Rule of Civil Procedure 1035);

b.) the propriety under Pennsylvania's Rule of Civil Procedure 1035, as construed by its courts, of considering documents submitted in untimely fashion in opposition to summary judgment, App. 13a-14a (citing three Pennsylvania Superior Court decisions);

c.) the adequacy of the solitary letter that could properly be considered in opposition to summary judgment to create a genuine issue of material fact sufficient to defeat summary judgment. App. 18a-20a (citing Pennsylvania R.C.P. 1035(d), a Pennsylvania Superior Court case and including an additional citation to a federal case *Ambrosini v. Labarraque*, 966 F.2d 1464 (D.C. Cir. 1992), discussed in Point III *infra.*, for language indicating that summary judgment may be proper where the affidavits of experts are insufficient to create a genuine issue of material fact); and

d.) the adequacy under Pennsylvania law of Upjohn's warning. App. 20a-24a (citing five Pennsylvania Supreme Court decisions).

The Pennsylvania Supreme Court simply denied leave to appeal. *App.* 1a-2a.

In sum, save for petitioners' belated and ineffective attempt to inject a federal issue — *any* federal issue — into the petition for leave to appeal to the Pennsylvania Supreme Court, there was no federal issue put before, or passed on by, any state court.

b.) Under Pennsylvania law, the purported constitutional issue was waived by failure to present it to the lower courts.

Pennsylvania requires that arguments made on appeal be preserved in the lower court from which the appeal has been

taken. Absent this, even constitutional arguments are deemed waived. "[E]ven constitutional issues such as failure to afford the parties due process of law may be waived where not raised in the lower court, but are presented for the first time on appeal." *Gerace v. Holmes Protection*, 516 A. 2d 354, 359 (Pa. Super. 1986) *allocatur denied* 527 A. 2d 541 (Pa. 1987); *See also In re Estate of Schmidt*, 596 A.2d 1124, 1131-2 (Pa. Super. 1991) *aff'd without opinion* 619 A.2d 1058 (Pa. 1993) (due process).

Here, as petitioners admit by their silence, no due process argument was made in the lower courts. Accordingly, to the extent that any was made to the Pennsylvania Supreme Court, it was improperly before that court and may not be considered here. *See, e.g., Bailey v. Anderson*, 326 U.S. 203, 206-207 (1945) (Supreme Court has no jurisdiction to consider federal question initially raised in petition for review filed in highest state court, where state court has refused to consider issues not raised below.)

c.) Even if it had been properly preserved for presentation to the Pennsylvania Supreme Court, petitioners' purported claim of a due process violation was insufficient to preserve that claim for review in this Court.

This Court does not review claims of federal constitutional questions that were not presented to lower state courts. A record from a lower state court must be clear on this point:

> At a minimum, however, there should be no doubt from the record that a claim under a *federal* statute or the *Federal* Constitution was presented in the state courts and that those courts were apprised of the nature and substance of the federal claim at the time and in the manner required by the state law. (emphasis in original)
>
> *Webb v. Webb*, 451 U.S. 493, 501 (1981).

The record here falls far short of this Court's minimum requirement. All that petitioners told the Pennsylvania Supreme Court was that the Superior Court's decision on an unspecified "question of substance" was not in accord with and contrary

to "applicable [and, again, unspecified] decisions of the Supreme Court of Pennsylvania and the Supreme Court of the United States." How the Pennsylvania Supreme Court could have divined that the due process claim presented in the instant Petition – itself somewhat murky[7] – was encompassed within the language relied upon by petitioners is difficult to say.

There is simply no way in which the Pennsylvania state courts can have had the opportunity required by comity to perform their duty of construing and applying the applicable federal requirements. *Webb, supra* 451 U.S. 499. Whether this Court is without jurisdiction to entertain the alleged federal claim or simply bound by a prudential rule not to do so, *See Banker's Life and Casualty Company v. Crenshaw*, 486 U.S. 71, 79 (1988), the result ought to be the same: denial of the Petition for Certiorari.

II. THE PETITION DOES NOT PRESENT A DUE PROCESS VIOLATION

a.) There is no substantive due process violation alleged here.

This Court recognizes a substantive component of the Fourteenth Amendment's Due Process Clause, U.S. Const. amend XIV §1, that protects rights deemed "fundamental", those "implicit in the concept of ordered liberty". *Palko v. Connecticut*, 302 U.S. 319, 325 (1937). These consist of most of the rights enumerated in the Bill of Rights and certain unenumerated rights appurtenant to them. *See, e.g., Planned Parenthood v. Casey*, __ U.S. __; 112 S. Ct. 2791, 2807 (1992).

Petitioners have failed to spell out any violation of any incorporated part of the Bill of Rights or any penumbral right.

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[7] The nature of petitioners' due process claim is never spelled out in the Petition. It is not clear whether they are asserting a deprivation of procedural due process (insufficient notice or opportunity to be heard); substantive due process (Pennsylvania's summary judgment, to the extent that it prevents trials, represents a denial of due process); or some mixture of the two. All that is clear is that they are dissatisfied with the result below and wish to have this Court change it.

Read most broadly, their petition seems to say that the Due Process Clause prohibits the use of summary judgment in place of trials. No court has so held and many courts have upheld the summary judgment process against various similar attacks. *E.g.*, *Pease v. Rathbun-Jones Engineering Company*, 243 U.S. 273 (1917) (sustaining summary judgment on surety bond against due process challenge); *Oglesby v. Terminal Transport Company, Inc.*, 543 F.2d 1111, 1113 (5th Cir. 1976) ("No constitutional right to a trial exists when after notice and a reasonable opportunity a party fails to make the rule-required demonstration that some dispute of material fact exists which a trial could resolve.")

b.) There is no procedural due process violation articulated in the Petition.

A procedural due process claim arises when there is a claim of a deprivation of a Constitutionally protected property interest or liberty interest without adequate notice and an opportunity to be heard. *E.g.*, *Bishop v. Wood*, 426 U.S. 341 (1976) (no liberty or property interest in employment). Leaving aside the issue of whether Pennsylvania is constitutionally required to provide causes of action for medical malpractice or product liability — or any sort of tort system at all — petitioners fail to make out any failure of notice or the opportunity to be heard before their claim was adjudicated. They had maintained claims substantially similar to those asserted here for some six years before the instant summary judgment motion practice. They had been forced to dismiss their claim on the eve of trial in 1988 for want of proof. Petitioners could not have been unaware that at some point in the proceedings they would have to substantiate their medical/scientific claims. When the motions were made in 1991, they had, as the Superior Court pointed out, *App.* 11a-14a, the opportunity and the obligation to show sufficient proof to defeat summary judgment or to request a continuance to marshal their proof. They did neither. They do not allege in their Petition that the courts below failed to give them an adequate opportunity to respond to the motion or adequate notice that it would be adjudicated.

In sum, Petitioners allege no deficiency in the notice or the sufficiency of their hearing. They simply dispute the correctness of the result reached. This does not amount to a violation of the U.S. Constitution.

c.) Petitioners do not have a due process right to a favorable decision in the state courts.

What petitioners are actually seeking from this Court is review of the Pennsylvania courts' decisions on state law. What this would do is federalize Pennsylvania's – and presumably every other state's – summary judgment law in the guise of a due process review. This Court has wisely rejected attempts to get it to take such steps. *E.g. Morley v. Lake Shore and Michigan Southern Railway Company*, 146 U.S. 162, 171-2 (1892): "[T]he adjudication of the plaintiff's claims by the courts of his own State must be admitted to be due process of law. Nor are we authorized by the Judiciary Act to review this judgment of the state court, because this judgment refuses to give effect to a valid contract or because such judgment in its effect impairs the obligation of a contract. If we did, every case decided in the state courts could be brought here, when the party setting up a contract alleged that the court took a different view of its obligation from that which he held." To abandon that position, as petitioners urge, is to invite every litigant unhappy with any aspect of a state court adjudication to urge it to this Court as a due process violation. "The Fourteenth Amendment does not guarantee that all decisions by state officials will be correct." *Lavine v. Milne*, 424 U.S. 577, 587 (1976). Petitioners here are asking this Court to rewrite the Fourteenth Amendment into such a guarantee and to be available to enforce the guarantee.[8] There is no need and no precedent for such a reading of the Due Process Clause or for such a role for this Court. The Petition should be denied.

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[8] Of course, even if the Fourteenth Amendment guaranteed correct results in the state courts, petitioners would be without a remedy in this Court. The result below was clearly correct under the law of Pennsylvania. Superior Court opinion, *passim*.

III. THE *AMBROSINI* CASE IS NOT GERMANE TO THIS PETITION

Petitioners make much of the supposed inconsistency between the result in this case and that in *Ambrosini v. Labarraque*, 966 F.2d 1464 (D.C. Cir. 1992). This claim, however, is based on a fundamental misunderstanding of that case as well as of the difference between the state and federal court systems in our country.

The issue before the *Ambrosini* court was the propriety, under the Federal Rules of Evidence and the Federal Rules of Civil Procedure, of a grant of summary judgment. In that case, the defendant moved for summary judgment on the basis that there was no reliable scientific evidence to support the contention that Depo Provera causes birth defects. Plaintiff opposed the motion by submitting affidavits from two experts. One expert, the same Dr. Goldman who supplied the letter in this lawsuit, stated in his affidavit that he was familiar with the available scientific and epidemiologic data concerning progesterone agents, including the product manufactured by the Upjohn Company known as Depo-Provera and that it was his opinion to a reasonable degree of medical and scientific certainty that the infant plaintiff's injuries were caused by the medication. Another expert, Dr. Brian Strom, supplied an affidavit to similar effect based on epidemiological data and stating that the methodology he used was one reasonably relied upon by epidemiologists. The district court granted summary judgment, finding that the affidavits were conclusory and did not meet the standard required by the District of Columbia Circuit in *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988) *cert. denied* 493 U.S. 882 (1989).

The *Ambrosini* court addressed two issues. The first was the degree of specificity required for an expert opinion under F. R. E. 705. It noted that the rule "eliminates the prior practice of requiring an expert to set out, specifically, the facts and data underlying an opinion before allowing the expert to testify. Under Rule 705, an expert's affidavit, no matter what the basis, cannot be excluded solely because it fails to disclose the facts

or data underlying the opinion." 966 F.2d 1468-1469 [citation omitted]. The second was the meaning of the words "specific facts" in F.R.C.P. 56(e). It held that the affidavit stating that, based upon a review of the scientific and epidemiological data and the medical records, the product caused the injuries complained of recited a "specific fact". Thus, if Dr. Goldman's affidavit was based upon scientifically reliable evidence sufficient to ensure its admissibility – a matter to be determined by the district court upon remand – it would suffice to defeat summary judgment. 966 F.2d 1470. The court specifically did not decide whether a bare conclusion that Depo-Provera had caused the infant's birth defects or the Strom affidavit, which concluded that progesterone causes birth defects in general, would have been sufficient to defeat summary judgment. 966 F.2d 1470-1471.

The Pennsylvania courts here faced a very different showing – as well as a different set of requirements – from that in *Ambrosini*. In *Ambrosini*, the plaintiffs submitted an affidavit. The petitioners here submitted only an unsworn letter, probably inadmissible under Pennsylvania law, but considered by the courts in the interest of fairness. *App.* 17a n.16. The *Ambrosini* affidavit recited that it was based upon "available scientific and epidemiological data" concerning the precise product in issue, as well as the medical records of the infant plaintiff. 966 F.2d 1465. The letter that petitioners submitted made no mention of scientific or epidemiological or any other literature – it simply recited a medical history and a conclusion. *App.* 34a-36a. In fact, the showing made here was less than the "bare conclusion that Depo-Provera caused Teresa's birth defects" that the *Ambrosini* court refused to decide was sufficient to satisfy Rule 56 because it was not even the sworn statement contemplated there. 966 F. 2d 1470. There is no sign in the *Ambrosini* opinion that the showing made here – an unsworn, naked conclusion – would have sufficed to defeat summary judgment. The court's reluctance to endorse either a bare conclusion or a nonspecific affidavit, such as Dr. Strom's, strongly suggests that it would have reached the same result as that of the Superior Court here.

Petitioners also fail to note the most important difference between the two cases: the procedural rules governing them. Under the federal rules, F.R.E. 705 permits an expert to state a conclusion without reciting the bases for it. Under Pennsylvania's rules, as the Superior Court noted, an expert, "in rendering an opinion, ...must set forth the specific facts and grounds relied upon which support the opinion." App. 14a. There is no requirement that Pennsylvania conform its procedural or evidentiary rules to those of the federal courts. It is "not bound by the United States Constitution to apply the Federal Rules of Evidence in its courts." *Duckworth v. Owen*, 452 U.S. 951 (1981) (Opinion of Rehnquist, J. and Burger, C.J., dissenting from denial of cert.). Petitioners have not made any showing that the result in this case would have been different under the federal rules or that, even if it would have been, the difference is a matter of constitutional importance.

CONCLUSION

For the reasons stated above, Upjohn respectfully requests that the instant Petition be denied.

Respectfully submitted,

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